

**REMARKS**

In response to the non-final Official Action of January 28, 2010, claims 1, 3, and 4 have been amended, withdrawn claim 34 has also been amended, and claim 2 has been canceled. Claim 2 has been canceled in view of the amendment to claim 1. Claim 34 has been amended in a manner to place it within Species I and therefore its consideration in the present application is respectfully requested. Support for this claim amendment is found in the original application as filed, including page 7, first full paragraph.

**Claim Rejections - 35 USC §103**

At pages 2-4, claims 1-4, 7-11, 15, 16, 19, 20, and 23-25 are rejected under 35 USC §103(a) as unpatentable over US patent 5,020,527, Dessertine, in view of WO 01/37909, Höerlins.

With respect to claim 1, the Office asserts that Dessertine discloses a dispenser for dispensing a substance in individual portions counted by a multi-use counter having a display incremented or decremented with the count portions dispensed and a dispense action detector for detection of the portion dispensing with the dispenser comprising a body having a dispensing orifice, as well as a container for the substance, the container being integral with or accompanied on the body, a mechanism in the body and/or the container for dispensing individual portions of the substance to the orifice, the mechanism having a displaceable element for initiating the dispensing action, and an accommodation on the body for the counter with its detector arranged for detection of dispensing action of the mechanism. Reliance is placed on Figures 1 and 4 of Dessertine and associated elements called out by the Office on pages 2-3 of the Action.

Höerlins is cited as disclosing a dispenser wherein the closure is adapted to co-operate with a portion of the body providing the accommodation with the assertion that it would be obvious to one of ordinary skill in the art at the time the invention was made to have modified the teaching of Dessertine to have included a closure adapted to co-operate with a portion of the body as taught by Höerlins and further enclosing the counter on the body because this would provide a cleaner ejection opening and a protected counter.

In view of the amendment to claim 1, applicant respectfully disagrees.

In particular, claim 1 has been amended to incorporate the feature of claim 2; namely, that the closure is tamper-evident. The Office asserts that this feature is disclosed in Höerlins, but for the reasons presented below, applicant respectfully disagrees.

An idea underlying the present invention is that dispensers for inhalers, and in particular metered dose inhalers, ideally comprise counters that indicate the number of doses of medicament remaining in the source in the dispenser. Such dispensers are advantageous because they allow users to know when they are likely to need a new source, when to carry a replacement, when to refill their prescription, etc.

Dispensers that have been used to date, however, can be fitted with a new counter at any stage, i.e., regardless of whether the source in the dispenser is new or is partially used or totally used. The latter is clearly dangerous because if the counter were to be fitted to a partially or totally used dispenser then there is a risk that the counter would indicate a number of doses left when in fact the dispenser is empty or emptier than indicated. This is described in the introduction of the present application (specification, page 3, first paragraph). There is therefore a need for safer dispensers.

This is achieved by the present invention by the provision of a dispenser having a temper-evident closure which cooperates with the body to removably enclose the counter. As shown in the Figures, the enclosure comprises a frangible portion that is ripped to remove the counter. This is central part 32 of end disc 23 as shown in Figures 1-4. Thus, if the counter is removed from the dispenser, the closure will show or indicate that a counter has been removed therefrom. This prevents a user from unwittingly inserting a new counter, or replacing a counter, in the belief that the source in the dispenser is full.

Neither of the cited documents discloses or suggests a dispenser having a tamper-evident closure as required by the amended claims.

Dessertine discloses a dispenser having a counter and timer unit for monitoring the number of spray doses dispensed by an inhaler. The unit 21 shown in Figure 4 includes an automatic counter chip with a long-life miniature battery which is activated by downward movement of the container 15 against a lever 23 connected to the unit 21. The operation of the unit is taught at column 3, lines 6-14. The unit 21 works by the lever 23 being swung downward to tick off a

dosage count on depression of the container 15, with the change in dosage count being displayed on the LCD screen 27 of the unit 21. This action simultaneously activates the timer which then signals a “beep” sixty seconds after the lever 23 has been depressed. Once a user has finished, the unit 21 may be simultaneously stopped and reset by depressing the reset button 29.

As acknowledged by the Office, Dessertine does not disclose a closure adapted to enclose a counter. Correspondingly, Dessertine also does not disclose or suggest a dispenser having an enclosure that is tamper-evident. Accordingly, applicant submits that the amended claims are distinguished over Dessertine.

The Office relies on Höerlins to teach the presence of an enclosure. Höerlins discloses a counting mechanism for counting the number of spray doses dispensed by an inhaler. The counter mechanism comprises a cap 7, a counting wheel 8 and a control wheel 9 and is mounted on the body of an inhaler as shown in Figure 1. The operation of the counting mechanism is shown in Figure 7. The mechanism works by depression of the can being detected by a pin 32 which forms part of the control wheel 9. Depression of the pin causes rotation of the control wheel 9 and via a gearing mechanism this causes the counting wheel 8 to be rotated. As a result of this latter rotation, a new display is shown through the indicator window 10 of the cap 7.

The Office argues that a person of ordinary skill in the art reading Höerlins would incorporate the cap 7 described therein into the device of Dessertine. Applicant respectfully disagrees. The cap 7 in Höerlins is a functional part of its counting mechanism as evidenced by the fact that it carries teeth on its interior (see Figure 2b). The teeth ensure that the counting wheel rotates by the correct amount and therefore that the correct dose is displayed through the indicator window of the cap. In contrast, the counting mechanism disclosed in Dessertine is based on an electronic counter. A person of ordinary skill in the art reading Höerlins would therefore not be motivated to incorporate its cap into Dessertine as it is not possible to incorporate the cap into its electronic counting mechanism. What, for example, would the teeth on the inside of the cap do? Moreover, applicant submits that neither Dessertine nor Höerlins discloses a dispenser having a tamper-evident enclosure as required by the amended claims. As discussed above, Dessertine does not disclose the presence of an enclosure at all. Furthermore, the counter described in Höerlins has an enclosure that can be removed and replaced freely and repeatedly. In Höerlins, the enclosure is

cap 7 which is coupled to the inhaler device via the mechanism shown in Figure 6 and described at page 12, paragraph 1 of the description. Essentially, the inhaler body is provided with flanges and the cap with an edge that cooperates with the flanges. It is clear that the cap can easily be removed from the inhaler device and then be put back thereon without any indication of it having been taken off. This teaches directly away from the invention now claimed wherein a key feature is that the enclosure be tamper-evident, i.e., it is clear when the enclosure has been opened to remove the counter.

In summary, it is respectfully submitted that a person of ordinary skill in the art would not combine the cap 7 of Höerlins into Dessertine because the cap 7 cannot fulfill its functional role in the Dessertine device. Moreover, applicant submits that even if a person of ordinary skill in the art and combine these teachings, he/she does not in any case arrive at the present invention now claimed as neither document teaches the presence of a tamper-evident enclosure. It is therefore submitted that the amended claims must be considered inventive.

It is therefore respectfully submitted that claim 1 is distinguished over Dessertine in view of Höerlins.

Dependent claims 3, 4, 7-11, 15, 16, 19, 20, and 23-25 are also believed to be distinguished over Dessertine in view of Höerlins at least in view of their ultimate dependency from amended claim 1.

Finally, applicant has amended dependent claim 34 to recite a dispenser as claimed in claim 1 comprising a multi-use counter. It is believed that this claim should be rejoined with the presently pending claims and should be found allowable in view of its dependency from claim 1.

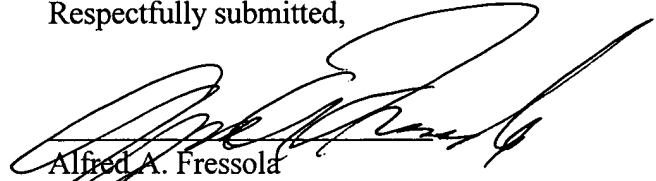
Furthermore, dependent method claims 32 and 33 should also be rejoined in view of the arguments in support of allowability of claim 1 from which these claims ultimately depend.

In view of the foregoing, it is respectfully submitted that the present application as amended is in condition for allowance and such action is earnestly solicited.

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The Commissioner is hereby authorized to charge to deposit account 23-0442 any fee deficiency required to submit this paper.

Respectfully submitted,



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